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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

3739

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 10/026,188	Applicant(s) Beil
Examiner <i>D. Shay</i>	Group Art Unit 3729

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE -2- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on July 27, 2003.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1-52 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-52 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-30, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15 exactly what is intended to be encompassed by the term “acellular organisms” is unclear, since claim 30 lists spores as acellular yet spores contain cytoplasm, which is defined in the art as material at the interior of a cell. Claims 36 and 37 are indefinite because it is unclear how the structure of the kit is changed or further limited by reciting the activity of the compound when placed in a particular environment.

Claims 1-3, 5-9, 11, 15-17, 19-25, 30-32, and 35-39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Vogel et al.

See column 11, line 8 to column 16, line 25.

Claims 1,4, 15, 18, 31, 33-35 and 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al ('020) in combination with Wilk et al ('675) and Vogel et al. Wilk et al ('020) teach sterilizing medical equipment such as catheters using light applied internally or externally of the surface. Wilk ('675) teach the use of the irradiation and a sterilizing solution. Vogel teach a solution as claimed that can be used in conjunction with light to kill bacteria or to treat viral conditions. It would have been obvious to the artisan of ordinary skill to employ in the method of Wilk et al ('675), the solution of Vogel et al and to sterilize the long dwelling catheters etc of Wilk et al ('020), upon which biofilms form and to employ the method on other body inserted lumens such as endotracheal tubes intravenous catheters, since these are equivalent

to the catheters of Wilk et al ('020) and since these are also recognized in the art as sites which require sterilization, thus producing a method such as claimed.

Claims 1, 5,10, 12-15, 20, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al in combination with Nitzan et al. Vogel et al teach a method of eradicating acellular or cellular organisms as claimed but does not teach adding the surface acting agent prior to the photosensitive material, or a plurality of photosensitive or surface acting agents or the light dosage rate. Nitzan et al teach a method of photosensitizing cells using a photosensitize surfactant mixture which will perform as claimed (The PMNP, which is made from Polymyxin B sulfate will retain some of the polymyxin B therein, and thus is considered a mixture of a plurality of surfactants) except for the specific time period between the addition of the two agents and the use of benzalkonium. It would have been obvious to the artisan of ordinary skill to employ benzalkonium chloride in the method of Nitzan et al, since this will inhibit bacterial and fungal contamination of the solution and to make the interval between the addition of the two agents between one and 30 minutes since this is not critical and would allow the membranes to be permiabilized prior to addition of the dye or alternatively to employ the surfactants, dosage rate, and photosensitive agents of Nitzan et al in the method of Vogel et al, since Vogel et al specifically state that surfactants may be added, since this would improve gel properties and also to employ the photosensitive agents since this would yield a composition also useful against gram negative bacteria, as taught by Nitzan et al, thus producing a method such as claimed.

The indefiniteness rejections have been maintained. That of "acellular" due to the inclusion of a spore (which has cell walls and cytoplasm see Wellinghoff et al column 1, lines

10-11) in the list of acellular organisms. That of claims 36 and 37 because these claims are drawn to a kit. The recitation of using the compound of the kit on particular organisms, does not infer any definitely defined modification to the structure of the kit.

Applicant argues that Vogel et al is not applicable under 35 USC 102 to the current claims because Vogel et al do not describe the action of benzalkonium chloride on the organisms to be photo dynamically treated as recited in the claims. However, since Vogel et al teach combining the benzalkonium chloride with the photosensitizer, and since Vogel et al discuss no means for a desirability of extracting the benzalkonium chloride from the photosensitizer before it is injected, the step of applying the compound of Vogel et al with inherently also apply the benzalkonium chloride as well and the surfactant will have the same effect on the cell membrane, regardless of the reason for which it was added to the compound. Thus even assuming Vogel et al were completely ignorant of the effect of benzalkonium chloride contemplated by applicant, thus effect, and thus the claimed disorienting, passing, and disruption would still inherently occur in the method of Vogel et al. Thus applicant's arguments regarding the lack of disclosure of Vogel et al are not convincing. Regarding the concentration of benzalkonium chloride, both applicants claims and the disclosure is originally filed are silent on the concentration of any compound or constituent thereof at the cell site, this argument is not persuasive.

The rejection involving Wilk et al ('020) has been amended to include the use of a sterilizing solution.

Regarding the combination of Vogel et al and Nitzan et al, applicant argues that Nitzan et al does not teach a method as claimed. Again applicant argues the mechanism of the chemical action is not that claimed. The examiner must disagree. Firstly it is noted that among the

ultrastructural changes of the cells treated with the mixture showed "a lytic process was developed in the treated cells" (page 92 column 2, last sentence of the this last full paragraph). According to applicants arguments, which assert that Nitzan et al only disclose binding of the photosensitizer to the cell membrane by the surfactant, this lytic process must occurs at the cell membrane. However, once the cell membrane is lyses or torn open (which would clearly constitute "disorienting the cell membrane so that said cell membrane no longer functions as an effective osmotic barrier " as claimed). Thus clearly Nitzan et al still teach a method as claimed even if the disclosure's wording is not that described in the claims ipsis verbis. Applicant then makes the totally unsupported assertion that Nitzan et al "teaches away from the concept of using photosensitizers and a surfactant such as benzalkonium chloride to increase cell membrane permeability and allow the photosensitizer to enter the cell by diffusion." The examiner challenges this totally unsupported statement, as applicant has not pointed to any statement by Nitzan et al regarding the inability of the composition to perform as claimed. Nor has applicant analyzed such statement in view of the nature of the teaching with respect to the totality of the teachings of the reference (see In re Gurley 31USPQ 2d 1130). Thus applicant must provide support for such a statement and analyze any supporting statement as to its substance if this line of argument is perused.

Applicant then alleges that there is no motivation whereby a person having ordinary skill would make the combination to achieve the claimed subject matter. The examiner notes that sufficient motivation has already been supplied. As an example thereof, applicant's attention is respectfully invited to page 3 lines 16-17 of the previous office action, which states in pertinent part the obviousness of using " benzalkonium chloride in the method of Nitzan et al since this

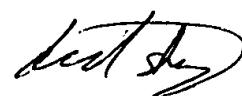
will inhibit bacterial and fungal contamination of the solution". It is the examiners view that there is ample motivation for the combination.

Regarding applicants demand for documentary proof that the PMNP of Nitzan et al would necessarily have Polymyxin B Sulfate therein, the examiner still asserts this fact, but also notes that the presence or absence of Polymyxin B in the PNMP is in material to the rejection as it now stands, since with the addition of benzalkonium chloride to the mixture of Nitzan et al, the mixture will contain a plurality of surfactants.

Applicant's arguments with respect to claims 1, 4, 15, 18, 31, 33-35, and 40-52 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed June 27, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.



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PRIMARY EXAMINER  
GROUP 330

Shay/DI

September 8, 2003